PATENT
Customer No. 22,852
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Todd J. MORTIER et al.	)	Group Art Unit: 3738
	)	
Application No.: 09/981,790	)	Examiner: D. Willse
	)	
Filed: October 19, 2001	)	
	)	
For: VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD	)	Confirmation No.: 6743

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request a pre-appeal brief review of the rejection in the final Office Action mailed April 18, 2005. The period for response has been extended to October 18, 2005, by a Petition and fee payment filed herewith. This submission complies with the requirements for requesting a pre-appeal brief review because: (1) this application has been at least twice rejected; (2) this Request is being filed with a Notice of Appeal prior to the filing of an Appeal Brief; and (3) this Request is five or less pages in length and sets forth legal and/or factual deficiencies in the final rejections. *See* Official Gazette Notice, July 12, 2005.

I. Status of the Claims

Claim 83 is the sole independent claim of examined claims 59-62, 64, 66-68, and 83-84. In the final Office Action, claims 64, 66, 67, and 83 were finally rejected under 35 U.S.C. § 102(b) as being anticipated by Alferness (U.S. Patent No. 5,702,343), and claims 59-62, 68, and 84 were objected to as being dependent upon a rejected base

claim, but allowable if rewritten in independent form.

II. Grounds for Traversing the Final Rejection

The final Office Action does not establish a *prima facie* case of anticipation in rejecting the claims over Alferness at least because Alferness does not disclose each and every aspect recited in independent claim 83. Claim 83 is directed to a method of treating an in situ mitral valve and recites:

> positioning a passive device with respect to a heart such that, ***throughout the cardiac cycle***, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve, ***wherein the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve.***

(Emphasis added.)

Alferness discloses a cardiac reinforcement device that provides reinforcement of the cardiac wall during only diastole by applying the device to the epicardial surface of the heart. *See, e.g.,* Alferness, col. 1, lines 8-14. Alferness explicitly teaches that the disclosed device does not provide cardiac assistance during systole, in contrast to prior art ventricular assistance devices. *See, e.g.,* Alferness, col. 3, lines 1-5, 11-14, and 33-38. Alferness further teaches that the disclosed device functions so as to reduce cardiac dilation and thereby potentially prevent or reduce problems that are associated with such dilation. *See, e.g.,* Alferness, col. 1, lines 25-30, and col. 5, lines 26-44.

There are therefore two independent reasons why Alferness fails to teach each and every element of independent claim 83. Specifically, Alferness neither discloses nor suggests, either explicitly or otherwise, that "throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure" or that "the passive device draws together leaflets of the in situ valve to promote closure of the in

situ valve," as recited in independent claim 83.

A. Alferness does not disclose devices that act "throughout the cardiac cycle"

Applicants' Request for Reconsideration After Final filed September 19, 2005, paper no. 20050919, at page 3, line 19 - page 7, line 13, fully explains why Alferness does not disclose devices that act "throughout the cardiac cycle." Those reasons are summarized here.

The Examiner alleges that the teaching of Alferness to position a cardiac reinforcement jacket device under the parietal pericardium is a teaching of "[altering] the geometry of the cardiac wall throughout the cardiac cycle by virtue of the device thickness shifting the cardiac wall inwardly from the parietal pericardium." *See* Office Action at page 2. Alferness, however, explicitly teaches to the contrary -- that the disclosed cardiac reinforcement device acts only during diastole and not during systole to provide cardiac reinforcement. *See* Alferness, col. 3, lines 1-5.

Furthermore, for the alleged altering of heart structure geometry throughout the cardiac cycle necessarily to occur, as required to establish inherency, the Alferness device at least would need a thickness sufficient to occupy the space between the heart and the parietal pericardium. Alferness, however, contains no disclosure in its text regarding the thickness of the disclosed device, and the Examiner has provided no evidence to support the assertion that the Alferness device necessarily has the thickness required to perform the alleged functions.

More than a possibility exists for the Alferness device to have a thickness whereby the device does ***not*** occupy sufficient space between the parietal percardium and the cardiac wall so as, allegedly, to shift the cardiac wall inwardly or otherwise alter heart structure geometry throughout the cardiac cycle. It is in fact unlikely that the

Alferness device possesses a thickness larger than the space between the pericardium and the myocardium. First, Alferness's figures, especially Figure 5, provide the only indication of the thickness of the disclosed device. That Figure shows the device to lie essentially flush with the heart surface (rather than having any appreciable thickness) and shows the device as having a thickness, for example, much less than a width of a main descending coronary vessel. Second, a device having a thickness larger than the space between the pericardium and the myocardium could result in excessive, uniform compression of the heart that could lead to undesirable cardiac tamponade.

B. Alferness does not disclose a "passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve"

As a second and independent basis to distinguish claim 83 over Alferness, Alferness does not disclose a "passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve," as fully explained in the Request for Reconsideration After Final at page 7, line 14 - page 10, line 6.

In the final Office Action, the Examiner alleges that col. 1, lines 25-30, and col. 5, lines 26-44 of Alferness teach that the disclosed devices of Alferness draw together leaflets of the in situ valve to promote closure of the in situ valve. However, rather than disclosing or otherwise suggesting a device that acts on the valve or draws together leaflets to close the valve, the cited passages, and the remainder of the disclosure of Alferness, describe a device that constrains cardiac expansion solely during diastole so as to prevent enlargement of the heart. At most, Alferness may be interpreted to teach that use of the disclosed cardiac reinforcement device for constraining cardiac expansion during diastole and preventing cardiac dilation may prevent the naturally occurring consequences of valvular leakage. This, however, is not a teaching of a

device that explicitly or inherently "draws together leaflets of the in situ valve to promote closure of the in situ valve." In other words, any reduction in valvular leakage in a heart equipped with a device disclosed by Alferness stems from a fortuitous, natural response of the heart to being constrained against excessive cardiac expansion, not from the Alferness device acting to draw the leaflets of a valve together.

Furthermore, as previously noted, Alferness discloses devices that only provide cardiac reinforcement during diastole, a period during which the mitral valve (which is recited in claim 83) is in a naturally open position, so as to allow blood to exit the left atrium and enter the left ventricle of a heart. Accordingly, it would be counterintuitive for the Alferness device to "draw together leaflets of [an] in situ valve to promote closure of the in situ valve" during diastolic filling, as alleged by the Examiner, because the device would urge the mitral valve to close when the valve is naturally designed to be open, which may hinder the natural functions of the heart.

III. Conclusion

As the rejection does not establish a *prima facie* case of anticipation, Applicants are entitled to a pre-appeal brief review of the final Office Action, and request that the claim rejection be withdrawn and the claims allowed.

Respectfully submitted,

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Dated: October 17, 2005

By _____
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